



METHODIST

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

IRB Office Only

Institutional Review Board Modification Form

This form is to provide an update to a previously approved Study.

IRB Meeting Date dd/mmm/yyyy

Attachment Completed By (initial / date)

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Methodist IRB ID#*

Date of Original Methodist IRB Approval*

Study Enrollment Status*

Open

Closed

Other

Total Subjects locally enrolled to date*

Total Subjects globally enrolled to date*

Method of Review Requested*

Expedited (The modification poses no more than minimal risk to Subjects.)

Full Board (The modification poses more than minimal risk to Subjects.)

Submission to IRB Date*

Modifications Requested

Minor Administrative Change

Protocol

Study Treatment or Conduct

Risks

Eligibility

Patient Facing Materials

(recruitment, educational, etc.)

Accrual

Other, _____

If Modifications requires changes to the existing ICF, complete next 3 questions.

Will currently enrolled subjects be required to re consent if this modification is approved?

If no, provide details.

No

N/A

Yes

Do the proposed changes materially effect the potential risks/benefits to Subjects?

If yes, provide details.

No

N/A

Yes

Will the proposed changes increase the participant's cost to participate in the study?

If yes, provide details.

No

N/A

Yes



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Documentation*

List any documents submitted with this request

Additional Information

Investigator's Certification*

I certify the provided information on this form is complete and accurate to the best of my knowledge. I will advise The Nebraska Methodist Institutional Review Board of any changes to the above completed fields when I become aware.

Signature of Principal Investigator or designee*/**

Printed Name of Principal Investigator or delegated staff*

Title of Principal Investigator or delegated staff*

Date (If not provided above)

* required field

** An electronic signature or typed name constitutes a binding electronic signature for this study.